

9 4 1 6 '01 FEB -2 P12:37

January 31, 2001

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Citizen Petition
Ifosfamide for Injection, USP

Dear Sir:

Attached are four (4) copies of a Citizen Petition seeking a determination whether the listed drug, IFEX[®], was withdrawn by Bristol-Myers Squibb for safety or effectiveness reasons.

If you have any questions, please call the undersigned at (708) 547-2384.

Yours Sincerely,



Tom Stothoff
2152 W. Potomac Ave.
Chicago, IL 60622
Tel: (773) 862-4923

OIP-0061

CP 1

CITIZEN PETITION

9420 '01 FEB -2 P12:37

The undersigned submits this petition under 21 CFR 10.30 and 314.122 to request the Commissioner of Food and Drugs to grant the Petitioner permission to file an Abbreviated New Drug Application (ANDA) for Ifosfamide for Injection, USP, which refers to a listed drug which has been voluntarily withdrawn from sale in the United States.

A. ACTION REQUESTED

This petition seeks a determination whether the listed drug, IFEX[®], was withdrawn by Bristol-Myers Squibb for safety or effectiveness reasons.

B. STATEMENT OF GROUNDS

The reference product, IFEX[®], has been discontinued by Bristol-Myers Squibb Company and is currently listed in the Approved Drug Products with Equivalence Evaluations (the "Orange Book") 20th Edition under "DISCONTINUED DRUG PRODUCT LIST". Provided in **Attachment 1** is a copy of the entry from the "Orange Book".

We intend to submit an Abbreviated New Drug Application (ANDA) for Ifosfamide for Injection, USP. The proposed product will be marketed in the identical configurations as the discontinued product, 1 gram/vial and 3 gram/vial.

C. ENVIRONMENTAL IMPACT

Action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement under 21 CFR 25.31 (a).

D. ECONOMIC IMPACT

Not Applicable

Citizen Petition
Ifosfamide for Injection, USP

E. CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all the information and views on which the petition relies, and that it included representative data and information known to the petitioner, which are unfavorable to the petition.

Tom Stothoff
2152 W. Potomac Ave.
Chicago, IL 60622
Tel: (773) 862-4923

ATTACHMENT 1

DISCONTINUED DRUG PRODUCT LIST

6-95

IBUPROFEN

TABLET; ORAL IBUPROFEN PUREPAC PHARM	400MG	N71124 001 SEP 19, 1986
	600MG	N71125 001 SEP 19, 1986
	800MG	N71964 001 FEB 01, 1988
SUPERPHARM	600MG	N70709 001 APR 25, 1986
TEVA	200MG	N73141 001 MAY 29, 1992
	400MG	N73343 001 JUN 30, 1992
	600MG	N73344 001 JUN 30, 1992
	800MG	N73345 001 JUN 30, 1992
ZENITH GOLDLINE	200MG	N71154 001 OCT 27, 1987
	200MG	N72040 001 APR 29, 1988
MIDOL BAYER	200MG	N70591 001 SEP 02, 1987
	200MG	N71001 001 SEP 02, 1987
NUPRIN BRISTOL MYERS	200MG	N72035 001 FEB 16, 1988
	200MG	N72036 001 FEB 16, 1988
RUFEN BASF	600MG	N18197 002 MAR 05, 1984

IDOXURIDINE

OINTMENT; OPHTHALMIC STOXIL SMITHKLINE BEECHAM	0.5%	N15868 001
SOLUTION/DROPS; OPHTHALMIC STOXIL SMITHKLINE BEECHAM	0.1%	N13934 001

IFOSFAMIDE

INJECTABLE; INJECTION IFEX BRISTOL MYERS SQUIBB	1GM/VIAL	N19763 001 DEC 30, 1988
	3GM/VIAL	N19763 002 DEC 30, 1988

IMIPRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION TOFRANIL NOVARTIS	12.5MG/ML	N11838 002
TABLET; ORAL IMIPRAMINE HCL CHELSEA LABS	10MG 25MG 50MG	N85875 001 N85878 001 N85877 001
EON	10MG 25MG 50MG	N85200 001 N84869 002 N85133 001
LEDERLE	10MG 25MG 50MG	N86269 001 N86267 001 N86268 001
ROSEMONT	25MG	N87776 001 FEB 10, 1982
VANGARD	10MG 25MG 50MG	N88036 001 NOV 03, 1982 N87619 001 FEB 09, 1982
	50MG	N87631 001 JAN 04, 1982
WATSON LAB	10MG 25MG 50MG	N85220 001 N84252 002 N85221 001
WEST WARD	25MG 50MG	N88222 001 MAY 26, 1983
	50MG	N88223 001 MAY 26, 1983
JANIMINE ABBOTT	10MG 25MG 50MG	N17895 001 N17895 002 N17895 003
PRAMINE ALRA	10MG 25MG	N83827 001 N83827 002

SHIPPING
AMERICAN PHARMACEUTICAL
2045 CORNELL AVE
MELROSE PARK IL 60160
(708)343-6100

SHIP DATE: 31JAN01
ACC# 227749237
ACTUAL WGT: 1 LBS MAN-WT

TO:
FDA DOCKETS MANAGEMENT BRANCH
12420 PARKLAWN DRIVE
ROOM 1-23
ROCKVILLE MD 20857

4433 1464 5206

FedEx

REF: 49407-841

****2DAY****

FRI

CAD# 0602159 31JAN01

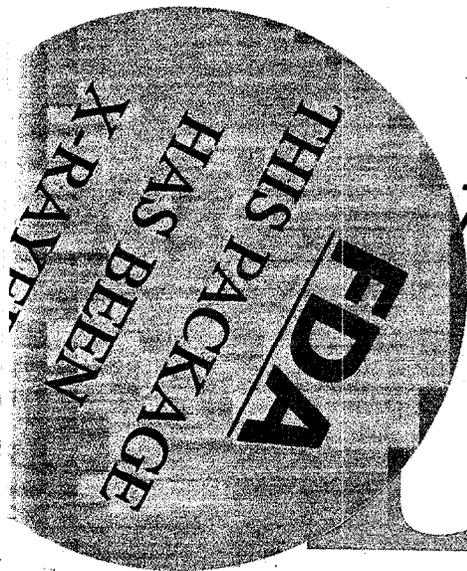
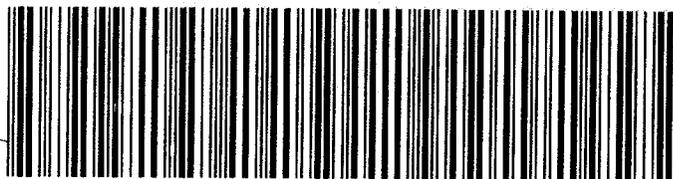
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